DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 6, 2014

Covidien, llc.
Saket Bhatt
Regulatory Affairs Manager
2000 Commonwealth Avenue, Suite 110
Auburndale, MA 02466-2008

Re: K141894
Trade/Device Name: SharkCore™ Fine Needle Biopsy System
Regulation Number: 21 CFR§ 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: FCG
Dated: September 11, 2014
Received: September 12, 2014

Dear Saket Bhatt,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
To be determined K141894

Device Name
SharkCore™ Fine Needle Biopsy System

Indications for Use *(Describe)*
The SharkCore™ Fine Needle Biopsy System is used with an ultrasound endoscope for fine needle biopsy, (FNB), of submucosal lesions, mediastinal masses, lymph nodes and intaperitoneal masses within or adjacent to the gastrointestinal tract. The needle is designed with a passive (i.e., automatic) safety shielding feature to aid in the prevention of needle stick injury.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5.0 510(k) SUMMARY

This 510(k) Summary for the SharkCore™ Fine Needle Biopsy System is being submitted in accordance with 21 CFR 807.92.

Submitter's Name, Address, Telephone Number and Contact Person

Covidien llc (formerly Beacon Endoscopic Corp.)
2000 Commonwealth Ave. Suite 110
Auburndale, MA 02466-2008

Contact: Saket Bhatt,
Regulatory Affairs Manager, Covidien llc
540 Oakmead Parkway,
Sunnyvale, CA, 94085

Phone: (408) 328-7357
Fax: (408) 328-7357 (same as phone#)

Date Prepared**:** July 10, 2014

Name of Medical Device:

SharkCore™ Fine Needle Biopsy System (includes Beacon™ EUS Delivery System and SharkCore™ FNB Needle)
Device Regulation: 21 CFR 876.1075, Class II
Product Code: FCG
Common/Usual Name: Kit, Needle, Biopsy (FCG)
Classification Panel: Gastroenterology-Urology Devices Panel

Establishment Registration Number, Owner/Operator Number:

Establishment Registration Number: 3009144059
Owner/Operator Number: 10037745

Predicate Devices

BNX Fine Needle Aspiration System (reference K133008, November 20, 2013)
EchoTip Ultra Ultrasound Needle (reference K083330; Feb 06, 2009)

Device Description

The SharkCore™ Fine Needle Biopsy (FNB) System is an echogenic biopsy needle used through the instrument channel of an ultrasound imaging endoscope. The system is used to sample targeted sub-mucosal and extramural gastrointestinal lesions through the accessory channel of an ultrasound endoscope. The SharkCore™ Fine Needle Biopsy (FNB) System is modular in design consisting of two major components; i.e., a delivery system (Beacon™ EUS Delivery System) and a separate exchangeable needle sub-assembly (SharkCore™ FNB Needle).

Indications for Use
The SharkCore™ Fine Needle Biopsy System is used with an ultrasound endoscope for fine needle biopsy, (FNB), of submucosal lesions, mediastinal masses, lymph nodes and intaperitoneal masses within or adjacent to the gastrointestinal tract. The needle is designed with a passive (i.e., automatic) safety shielding feature to aid in the prevention of needle stick injury.

Technological Characteristics Compared to Predicate Devices
The SharkCore™ Fine Needle Biopsy System is identical to the legally marketed BNX™ Fine Needle Aspiration System (reference K133008) in terms of principle of operation, technological and performance characteristics (control mechanism, environmental specifications, dimensional specifications, ergonomics of patient-user interface, packaging, sterilization and shelf life), materials, anatomical site, operating instructions, and single-use disposition. The SharkCore Fine Needle Biopsy System is substantially equivalent to the legally marketed EchoTip Ultra Ultrasound Needle (reference K083330; Feb 06, 2009) in terms of indications for use, anatomical location of use and labeling.

Performance Data
Bench testing demonstrates performance equivalence for the SharkCore FNB system when evaluated against its predicate devices.

Conclusion
Covidien llc considers the SharkCore™ Fine Needle Biopsy System to be substantially equivalent to legally marketed predicate devices BNX Fine Needle Aspiration System (reference K133008, November 20, 2013), and EchoTip Ultra Ultrasound Needle (reference K083330; Feb 06, 2009). The test results and compliance with applicable standards provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its indications for use.